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Dated: 3/11/05

Signature:

Andrea Berlo
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Docket No.: MIY-P04-006
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gellman et al.

Application No.: 10/774842

Confirmation No.: 1110

Filed: February 9, 2004

Art Unit: 3763

For: DEVICES FOR MINIMALLY INVASIVE
PELVIC SURGERY

Examiner: Not Yet Assigned

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each foreign patent reference and non patent literature on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent,

publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Supplemental Searches

Subsequent to the pre-examination searches performed by Applicants and reported in the Petition to Make Special filed on September 13, 2004, the following additional searches were performed:

1. We employed a third party, the Danish Patent and Trademark Office, to conduct an independent search of the patent and non-patent literature for medical devices having a mesh or tape enclosed in a sleeve or pouch, particularly a plastic sleeve or pouch, wherein the mesh or tape is for implanting in the body. This search was performed using the on-line patent databases WPI and EPODOC. Non-patent literature databases searched include NPL, COMPENDEX, and INSPEC. These databases were searched for the following terms, wherein * is a wildcard denoting any additional characters:

- 1) implant* or medical*
- 2) tape* or mesh* or screen* or strip*
- 3) sleeve* or sheath* or pouch* or envelop* or casing or tub*
- 4) enclos* or cover* or encas* or surround* or encircl* or enfold*

The above terms were used with synonyms in relevant combinations and truncations. The Danish search produced 17 references: U.S. Patent No. 4,580,568; U.S. Patent No. 4,629,458; U.S. Patent No. 4,665,918; U.S. Patent No. 4,878,906; U.S. Patent No. 4,950,227; U.S. Patent No. 5,026,377; U.S. Patent No. 5,078,720; U.S. Patent No. 5,290,295; U.S. Patent No. 5,330,500; U.S. Patent No. 5,354,310; U.S. Patent No. 5,405,380; U.S. Patent No. 5,456,721; DE 43 02 693; GB 1,205,743; JP 6,189,984; EP 0311305; and WO 94/01056, which are summarized below. It should be noted that the search performed by the Danish Patent and Trademark Office was limited to publications prior 1996.

2. We also performed the following miscellaneous searches for non-patent references:

- 1) On-line search on the website PUBMED with the search parameters: (sling* or mesh or tape or tapes) and (incontinence or urinary or hernia* or hernio*) and enclosing or enclose* or encircle* or encasing or enfold* or surround*) and date (1992/1/1-1995/10/10), wherein * is a wildcard denoting any additional characters.
- 2) Author searches:
 - a. U. Ulmsten, L. Henriksson, P. Johnson, G. Varhos, Petros P, Falconer C, Rezapour M. (date limit: 1/1/1992 - 10/10/1995)
 - b. R. Scott, D. Gorham, M. Aitcheson, S.P. Bramwell, M.J. Speakman, R.N. Meddings
 - c. F. Benderer; Barry Gellman
- 3) Hand searches:
 - a. *J. Urology* (1992-1995) under the subject index “incontinence” and “urinary incontinence”
 - b. American Urological Association (AUA) (1992-1995) Annual conference abstracts under subject index “incontinence” and “urinary incontinence”
- 4) Conference abstracts searches:
 - a. Proceedings of the International Continence Society Annual Meetings 1992-1995
 - b. The American Urogynecologic Society Annual Meeting 1995
 - c. The International Urogynecological Association Annual Meetings 1994-1995
- 5) FDA medical device database searches – 510(k) Premarket Notification Database
 - a. “Ethicon” in <Applicant> field and “mesh” in <Device Name>
 - b. “TVT” or “tension free vaginal tape” in <Device Name>

These miscellaneous searches afforded 3 additional references: Amid et al., “Experimental Evaluation of a New Composite Mesh with the Selective Property of Incorporation to the Abdominal Wall without Adhering to the Intestines,” *J. Biomedical Materials Research*, 28: 373-375 (approx March 1994); Carachi R. et al., “Collagen-Coated

Vicryl Mesh: A New Bioprosthesis in Pediatric Surgical Practice,” *Journal of Pediatric Surgery*, 30: 1302-1305 (September, 1995); and Ulmsten U., et al., “An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence,” *International Urogynecology Journal*, 7:81-86 (approx. March 1996), which are summarized below.

With respect to the subject matter of the references found during the searches, Applicants submit the following:

1. Amid et al., *Journal of Biomedical Materials Research*, Vol. 28, pages 373-375, approx. March 1994 – This reference is entitled “Experimental Evaluation of a New Composite Mesh with the Selective Property of Incorporation to the Abdominal Wall without Adhering to the Intestines.” This reference reports the results of a study on a new composite mesh that examined the possibility of preventing intestinal adhesions to biomaterials while preserving their incorporation with the abdominal wall. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

2. Carachi R. et al., *Journal of Pediatric Surgery*, Vol. 30, pages 1302-1305, September, 1995 – This reference is entitled “Collagen-Coated Vicryl Mesh: A New Bioprosthesis in Pediatric Surgical Practice.” This reference discloses a study in which patients were treated for thoracic and abdominal wall defects with a collagen-coated Vicryl mesh. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

3. Ulmsten U. et al., *International Urogynecology Journal*, Vol. 7, pages 81-86, approx. March 1996 – This reference is entitled “An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence.” This reference reports the results of

a prospective study for a modified intravaginal slingplasty for the surgical treatment of female stress incontinence. Figure 1 discloses a prolene gauze sling, covered by a plastic sheath, fixed to two metal or plastic disposable needles. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

4. U.S. Patent No. 4,580,568 – This reference generally relates to an endovascular stent formed of stainless steel wire and arranged in a closed zigzag pattern. As shown in Figure 1, the stent 9 includes a length 10 of stainless steel wire formed in a closed zigzag configuration. The wire is closed by a sleeve 11 which is welded to or tightly squeezed against the ends of the wire to produce an endless configuration. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

5. U.S. Patent No. 4,629,458 – This reference generally relates to a reinforced graft particularly adapted for cardiovascular use. As described in Figures 6 and 7, to provide a graft 40 which has an extra degree of reinforcement, a mesh screen may be placed around the rod 36 within the coil 34 before the graft 40 is formed to provide a further reinforcement to the cylindrical wall 42 of the graft 40 and to provide another surface within which the collagen 43 can grow and to which it can attach itself. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

6. U.S. Patent No. 4,665,918 – This reference generally relates to a system and method for implanting a prosthesis in the length of a blood vessel. As shown in Figure 1, the sheath 50 includes a central lumen 56 dimensioned to fit over the outside periphery of the prosthesis delivery catheter 18. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

7. U.S. Patent No. 4,878,906 – This reference generally relates to a prosthesis consisting of a flexible thin-walled sleeve for reinforcing and repairing a damaged vessel and a process of placing the flexible sleeve in the vessel. Figures 1 and 2 illustrate a sleeve in which the reinforcing ribs run diagonally across the outer surface of the sleeve. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

8. U.S. Patent No. 4,950,227 – This reference generally relates to a stent delivery system to facilitate introduction and placement of a stent. As shown in Figure 1, a stent 16 is fixed about a balloon 14 by two overlying retaining sleeves 18 and 20. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

9. U.S. Patent No. 5,026,377 – This reference generally relates to and instrument for the deployment or retraction of a self-expanding stent in a body canal. As shown in Figure 1, an outer sleeve 1 has an integral handle 2 at its proximal end. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a

curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

10. U.S. Patent No. 5,078,720 – This reference generally relates to an instrument for the placement of a self-expanding stent in a body canal. As shown in Figure 1, a hollow outer tube 6 disposed about the inner tube along the axis thereof and slidably positioned around the inner tube 4 carries a self-expanding stent 7. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

11. U.S. Patent No. 5,290,295 – This reference generally relates to an apparatus for the intraluminal insertion and deployment of a medical graft within a blood vessel. As shown in Figure 1, a tool 10 is designed to carry graft 14 into the body on an insertion shaft 18, while graft 14 is covered by a shield, or sheath 19 as tool 10 is advanced within the body. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

12. U.S. Patent No. 5,330,500 – This reference generally relates to a self-expanding endovascular stent with silicone coating. As shown in Figure 2, the stent comprises a cylindrical main frame of a first diameter comprising a plurality of unit structures, each unit structure formed in an endless zigzag configuration. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and

withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

13. U.S. Patent No. 5,354,310 – This reference generally relates to an implantable medical device, including an elongated, expandable tubular mesh that can be used to bring a temporary graft into position against an inner wall lining of a blood vessel. As seen in Figures 1 and 2, the device 10 is placed within the aortic artery by means of an elongated placement catheter 12 having an elongated, tubular sheath which enters the patient through the femoral artery in the patient's leg. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

14. U.S. Patent No. 5,405,380 – This reference generally relates to a catheter with a radially self-expanding cylindrical vascular support made of a permeable mesh of crossed stiff fibers. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

15. U.S. Patent No. 5,456,721 – This reference generally relates to an apparatus for reinforcing a ligament transplant during reconstructive surgery. The apparatus is a sheath knitted in a thread made of resorbable material, designed to sheathe the transplant and the bank tendon. As shown in Figure 1, the sheath 1 is knitted with a thread 10 of resorbable material. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

16. DE 43 02 693 – This reference generally relates to a guide wire. As shown in Figure 1, the guide wire structure has an outer covering at least partially, round the shrouding 2, using an oriented film ribbon 3 of a fluoro polymer. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

17. GB 1,205,743 – This reference generally relates to surgical dilators and, in particular, to an oesophageal dilator. As shown in Figure 1, the dialator comprises a hollow tubular member the wall of which is defined by a tubular core 1 of lattice form embedded in a continuous tubular layer 3 of a resilient material such as rubber. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

18. JP 6,189,984 – This reference generally relates to an artificial blood vessel and manufacture thereof. As can be seen in Figure 1, a tubular resin fluoride coating layer 2 having mesh-like holes 4 is laid on the external surface of a tubular tetrafluoroethylene resin porous body 1. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

19. EP 0 311 305 – This reference generally relates to an artificial blood vessel capable of growing having a collagen tube made mainly of collagen which is lightly crosslinked with a crosslinking agent and a mesh tube covering the outer surface of the collagen tube. This reference does not appear to teach a method for treating female urinary incontinence comprising,

inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

20. WO 94/01056 – This reference generally relates to a tubular medical prosthesis with improved properties by forming the prostheses of multiple filaments or strands of different materials. Multiples strands of different materials are co-knit into a stent. As illustrated in Figure 1, a graft 10 is formed of loosely interlocked knitted loops of material. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

Summaries of Art Cited in Supplemental IDS filed September 22, 2004

Additionally, in light of the Petition to Make Special filed on September 13, 2004, Applicants submit herein summaries of the art cited in the Supplemental IDS filed September 22, 2004. A copy of the corresponding PTO/SB/08 is provided.

With respect to the subject matter of the references in the Supplemental IDS filed September 22, 2004, Applicants submit the following:

1. U.S. Patent No. 3,551,987 (Cite No. AA) – This reference generally relates to a surgical clamp for simultaneous setting of multiple staples in the suturing of resected stomachs and other gastrointestinal surgery, embodying jaws of Z-offset form, and jaw-closing means utilizing fluid or electromagnetic or equivalent power operation. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

2. U.S. Patent No. 3,575,163 (Cite No. AB) - This reference generally relates to a speculum for examining body orifices or cavities and more particularly to a vaginal speculum of disposable two-piece construction with variable proximal end openings and multiple distal end opening adjustments. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

3. U.S. Patent No. 3,744,481 (Cite No. AC) - This reference generally relates to a device for viewing the cervic and vaginal segment of a human uterus. One embodiment provides a manually portable medical instrument consisting of device 10, generally comprising a handle 12, a hollow housing 14 mounted thereon, and a plurality of blades 16, 18, and 20 releasably secured to the housing. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

4. U.S. Patent No. 3,762,400 (Cite No. AD) - This reference generally relates to a device for viewing the cervix and vaginal segment of a human uterus which has a plurality of blades removably mounted on a holder. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

5. U.S. Patent No. 4,935,027 (Cite No. AE) - This reference generally relates to surgical suturing instruments that are controllable from a position remote from the surgical site to effect tissue suturing at the surgical site. In one embodiment, the invention provides for continuous feed of suture material through opposed forcep jaw members between which the tissue segments

are interposed to expedite the suturing process and enable suturing to be accomplished at remote internal sites of the body incident to various endoscopic procedures. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

6. U.S. Patent No. 4,991,578 (Cite No. AF) – This reference generally relates to implantable defibrillation leads and electrodes and to methods for the sub-xiphoid implantation of deployable defibrillation electrodes, and means for anchoring the same to tissue within the pericardium. In one embodiment, a guide wire is inserted into the pericardium through the lumen of a needle, and while the guide wire remains in the pericardial space, the needle is removed. A sheath is introduced over the guide wire, with the aid of a dilator, and inserted into the tissue until one end thereof is positioned within the pericardium. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

7. U.S. Patent No. 5,064,434 (Cite No. AG) - This reference generally relates to an apparatus, a non-surgical hypodermically implanted genitourinary prosthesis. The apparatus includes an expandable containment membrane 4 for being hypodermically implanted into the patient. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

8. U.S. Patent No. 5,122,130 (Cite No. AH) - This reference generally relates to a surgical instrument set for the insertion of intervertebral endoprostheses, which consist of two

stop plates and a sliding core to be arranged between them. As can be seen from FIG. 1, in one embodiment, a spreading forceps 9 which has, at its front end on each spreading jaw 10 and 11, an essentially U-shaped recess surrounding one stop plate on three sides and gripping the edge, the thickness of the spreading jaws 10 and 11 in the spreading direction being essentially identical to the thickness of the stop plates. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

9. U.S. Patent No. 5,165,387 (Cite No. AI) - This reference generally relates to endoscopes having a light source for inspection through a vagina. A disposable endoscope kit 10 has a speculum member 22 and a disposable light source 24. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

10. U.S. Patent No. 5,179,937 (Cite No. AJ) - This reference generally relates to a disposable speculum used for inspection of vaginal walls and the cervix uteri. The speculum comprises two dilation blade members which are attached to each other and movable apart. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

11. U.S. Patent No. 5,237,985 (Cite No. AK) – This reference generally relates to a device for positioning and controlling the uterus, and viewing the vaginal cuff, within the abdominal cavity to aid in medical procedures. One embodiment provides a uterine retractor having an elongated insertion rod having at a rear end a ratchet handle which may be rotated.

This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

12. U.S. Patent No. 5,300,082 (Cite No. AL) - This reference generally relates to surgical instruments for use during laparoscopic surgery, in particular to a needle holder for use inside the abdominal cavity. The instrument has a surgeon operable control handle for grasping surgical needles or other objects. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

13. U.S. Patent No. 5,308,349 (Cite No. AM) - This reference generally relates to methods for performing knee surgery and to retractors and a femoral distractor for use in performing such surgery. The retractors include a PCL tibial retractor, lateral patellar retractor. Collateral ligament retractor, posterior cruciate ligament retractor and unicompartmental retractor designed to cooperate with one another in performing such method. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

14. U.S. Patent No. 5,330,496 (Cite No. AN) - This reference generally relates to a vascular catheter assembly for penetration through tissue (more specifically blunt boring) and for cardiac stimulation, and methods thereof. The apparatus includes a tubular member having a lumen, and a blunt-end stylet within the lumen. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved

portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

15. U.S. Patent No. 5,336,231 (Cite No. AO) - This reference generally relates to a laparoscopic surgical ligation device which provides means for positioning a tissue to be ligated, repairing a tissue, completing a ligation and for coagulation and fulguration of a ligated tissue. The device has a central passageway with first and second parallel channels on opposite sides thereof. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

16. U.S. Patent No. 5,397,330 (Cite No. AP) - This reference generally relates to methods for performing knee surgery and to retractors and a femoral distractor for use in performing such surgery. The retractors include a PCL tibial retractor, lateral patellar retractor, collateral ligament retractor, posterior cruciate ligament retractor and unicompartmental retractor designed to cooperate with one another in performing such method. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

17. U.S. Patent No. 5,437,603 (Cite No. AQ) - This reference generally relates to an apparatus for directing a hypo-dermic instrument to a predetermined target location within the periurethral tissues and to an apparatus and method for implanting a device or injecting a substance at a predetermined target location within the periurethral tissues. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient;

associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

18. U.S. Patent No. 5,462,560 (Cite No. AR) - This reference generally relates to medical devices used to close surgical wounds, and in particular to a fixed double-needle ligature device particularly useful for creating circumferential ligatures as are needed in, for example, laparoscopic surgery. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

19. U.S. Patent No. 5,536,251 (Cite No. AS) - This reference generally relates to less-invasive surgical instruments for clamping, cannulation of, and infusion of fluids into hollow body structures. The invention provides devices and methods for thoracoscopically arresting the heart and establishing cardiopulmonary bypass. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

20. U.S. Patent No. 5,582,188 (Cite No. AT) - This reference generally relates to methods of tensioning a suspended tissue mass. One embodiment provides a drill guide for directing a drill bit at a selected site on a bone. Another embodiment provides a drill guide for use in locating drill sites in a patient's body. Another embodiment provides a method of positioning a drill guide over a drilling site on bone. Another embodiment provides a method of installing a bone anchor in a bone. Another embodiment provides a suture passer of the type adapted for releasably retaining a suture. Another embodiment provides a drape and exposure system. Another embodiment provides a suture support for providing a structure to which sutures may be anchored inside the body so as to reduce trauma to body tissue. This reference does not appear

to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

21. U.S. Patent No. 6,258,024 (Cite No. AU) - This reference generally relates to dilating speculums used for dilating body cavities and/or the orifices thereof so as to facilitate examinations of, or operations within, the interior of the cavity. In one embodiment, a probe for a speculum for use in examining the interior of a body cavity is described. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

22. EP 0 417 031 (Cite No. BA) - This reference generally relates to a method and apparatus for providing intrapericardial access and inserting intrapericardial electrodes. The reference provides a method for intrapericardial access by clamping the wall of the pericardium between elongate jaw elements carrying axially aligned tubular guides and passing a guide wire through the guides and the pericardial tissue therebetween. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

23. EP 0654 247 (Cite No. BB) - This reference generally relates to endoscopic surgery at locations in the body where tissue inserts into bone and more particularly to a method and system of performing endoscopic heel surgery. The endoscopic system 20 for performing endoscopic surgery at locations where tissue inserts into bone which includes a sleeve member 22, obturator 24, cutting 110 and excision instruments 160, and a marking and insertion

assembly 230 wherein the sleeve member 22 has an expander portal 44 through which instrument access and improved visualization can be performed at arcuate lines of insertion of tissue into bone. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

24. EP 0 407 357 (Cite No. BC) – This reference generally relates to medical instruments designed for inspection of those passages of the human body affording an external opening, and in particular the vagina, such as a disposable vaginal speculum. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

25. GB 2,214,814 (Cite No. BD) - This reference generally relates to an apparatus for passing a wire, suture or the like behind a bone or other obstacle during surgery. The device comprises a pincers-like device of which the jaws 8, 10 comprise tubes open at their free ends 20, 22 and each having an opening 32 spaced from its free end. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

26. WO 94/12091 (Cite No. BE) - This reference generally relates to a speculum 700 for dilating a body cavity including a base 706 and a number of arms 710 pivotably attached to the base 706. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft

subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

27. WO 96/06567 (Cite No. BF) - This reference generally relates to a surgical instrument and a method for treating female urinary incontinence. The instrument comprises a shank 10 having a handle 11 at one end thereof, and two curved needle-like elements 21A and 21B which are connected at one end thereof each with one end of a tape 26 intended to be implanted into the body. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

28. WO 96/28083 (Cite No. BG) - This reference generally relates to a speculum 10 comprising a plurality of dilator fingers 12, 14, 16, and 18 which are disposed about and pivotally compound to a support 20. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

29. "The Preurethral Cutter Clamp," Lone Star Medical Products, Inc. Catalog, 2 pages (Cite No. CA) - This reference generally relates to a device for cutting or dissecting tissue around the urethra or bladder neck. The blade of the device carries a sutures that can be used to guide other instruments, material or fascia into position. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

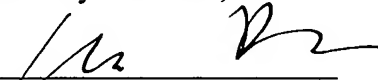
30. International Search Report for PCT/US98/03065 (Cite No. CB) - This reference reports two references which were found by the International Searching Authority in the course of prosecution of the above application. This reference and those it discloses do not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

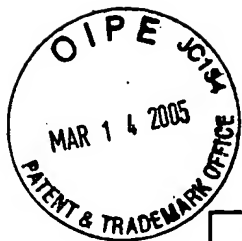
31. Mitchel, British Journal of Urology, Vol. 42, pages 599-600, 1970 (Cite No. CC) – This reference is entitled “Hook Needle and Retractor for Posterior Urethroplasty.” This reference generally relates to devices for posterior urethroplasty. One device comprises a curved needle for insertion of a suture into the posterior urethral wall in the region of the verumonatanum. Another device is a speculum which comprises two lugs to hold the device in place. This reference does not appear to teach a method for treating female urinary incontinence comprising, inserting a shaft having a curved portion percutaneously into a body and through a vaginal wall of a patient; associating a sling assembly end with an end of the shaft subsequent to the shaft extending through the vaginal wall; and withdrawing the shaft to place at least a portion of the sling assembly under a urethra of the patient.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P04-006. A duplicate copy of this paper is enclosed.

Dated: March 11, 2005

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| | | | | Application Number | 10/774,842 |
| | | | | Filing Date | February 9, 2004 |
| | | | | First Named Inventor | Barry N. Gellman |
| | | | | Art Unit | 3763 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 2 | Attorney Docket Number | MIY-P04-006 |

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Application No. (if known): 10/774842

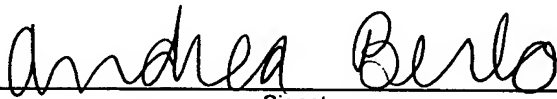
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